

### **Remarks**

The Office Action mailed July 1, 2003 has been received and reviewed. The application is to be amended as previously set forth. In order to expedite prosecution, all pending claims except claim 28 are to be canceled without prejudice or disclaimer. New claim 48 is to be added. All amendments are also made without prejudice or disclaimer. Claim 28 is rejected. Reconsideration is respectfully requested.

#### **A. Election / Restrictions:**

Claims 27, 31, and 47 were withdrawn as being independent from the elected invention. In order to expedite prosecution, these claims have been canceled, thus mooted the issue and obviating the need to respond.

#### **B. 35 USC § 102:**

Claims 1-23 and 38-45 were rejected under 35 USC § 102 as being anticipated by Crystal et al. (U.S. Patent 6,127,525). As these claims have been canceled herein, no need remains to respond to the rejections.

Similarly, claims 1-13, 18-19, 21, and 38-41 were rejected under 35 USC § 102 as being anticipated by JP02000157289A1. As these claims have been canceled herein, no need remains to respond to the rejections.

#### **C. 35 USC § 112, 2<sup>nd</sup> ¶:**

Claims 1-23, 28, and 38 through 46 were rejected as assertedly being indefinite under the second paragraph of 35 USC § 112. All of these claims except claim 28 are to be canceled, thus obviating the need to respond to those aspects of the rejection.

With respect to claim 28, it was thought vague use of "derivative" language. The amended claim no longer uses the rejected language and applicants thus request that the rejection be withdrawn.

#### **D. 35 USC § 112, 1<sup>st</sup> ¶:**

Claims 3-23, 28, and 38-46 were rejected under the first paragraph of 35 USC § 112 as

assertedly lacking adequate written description. Claim 43 was additionally rejected under 35 USC 112, first paragraph, as assertedly lacking enablement. In order to expedite prosecution, all of the rejected claims except claim 28 have been canceled, thus obviating the need to respond to those aspects of the rejection.

With respect to claim 28, one aspect of the rejection evidently related to use of "derivative" terminology. (Paper No. 11, p. 10). As stated previously with respect to the rejection under the second paragraph of 35 U.S.C. § 112, that language has been removed from the amended claim, so the rejection should be overcome.

The remainder of the rejection evidently related to the breadth of the claims, *i.e.*, "genus claims". Claim 28 has been amended to recite that the "recombinant adenovirus's fiber comprises: at least one protein fragment of an adenovirus serotype of subgroup C, and at least a knob domain of a fiber protein of a second adenovirus serotype associated therewith, wherein the second adenovirus serotype is selected from the group consisting of serotype 16, serotype 32, serotype 35, serotype 40-S, and serotype 51". New claim 51 specifically defines the adenovirus serotype of subgroup C to be adenovirus serotype 5, which should certainly overcome the rejection as regards this claim.

Figure 1 of the application as-filed shows that there are 5 serotypes better able, in comparison to Ad5 itself, to infect mesenchymal stem cells, namely Ad16, Ad32, Ad35, Ad40-S and Ad51 (Ad51 is even better than Ad16). It is thus respectfully submitted that no new matter has been added by the amendment.

Applicants respectfully point out that it is not essential that adenovirus serotype 5 be used as a backbone vector. Subgroup C is a very useful backbone vector since the members are well known and can be easily produced to high titers on available packaging cells, as are the other members of subgroup C. Other serotypes may encounter problems in that regard. The fiber knob used is what is important to the claimed method of delivering a nucleic acid of interest to the target cells. The prior art is silent about which fiber to use in the claimed method, and the inventors hereof were the first to show that these specific serotypes were highly useful.

After reviewing applicants' disclosure, a person of skill in the art can readily determine the knob domain from any known (or new) adenovirus serotype by comparing the fiber amino

acid sequences of all known serotypes and by reading the literature about fiber functions. A significant number of articles have been published that deal with the positions of the tail, shaft, and knob domains within the fiber protein. The knob domain can therefore be easily distinguished from the shaft and tail of any known and new serotype.

In view of the foregoing, applicants request that the rejection be withdrawn.

#### Conclusion

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Allen C. Turner".

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